**REMARKS**

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-10 are pending in the present application. Claims 1-9 have been amended to address the formal matters raised in the outstanding Official Action. New claim 10 has been added. Support for claim 10 may be found in original claims 1 and 2-4.

In the outstanding Official Action, the Official Action stated that the GORTNER et al. and McCAY et al. publications were not considered because copies of the publications were not provided. In the interest of advancing prosecution, the GORTNER et al. and McCAY et al. publications are attached with the present amendment. However, applicant notes that both the GORTNER et al. and McCAY et al. publications were utilized in a 35 USC §103 rejection imposed in the outstanding Official Action. As a result, applicant believes that the publications have been considered. If this is not the case, the Examiner is respectfully invited to contact the undersigned so that this issue may be promptly addressed.

In the outstanding Official Action, claims 1-9 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the present invention. Applicant believes that the present amendment obviates this rejection.

In imposing the rejection, the Official Action alleged that the phrase "Compositions for stomatological use containing as active ingredients compounds of rhubarb *(Rheum genus)* and *Spinacia oleacea L.*" and "wherein the plant compounds" were indefinite.

However, claim 1 has been amended so that the phrase "Compositions for stomatological use containing as active ingredients compounds of rhubarb *(Rheum genus)* and *Spinacia oleacea L.*" is no longer recited. Moreover, applicant believes that claim 1 has been amended to provide antecedent basis to the phrase "wherein the plant compounds" that is recited in claims 2-4. As a result, applicant believes that claims 1-4 are definite to one of ordinary skill in the art.

Claim 6 was rejected for allegedly reciting a "use" without reciting steps involved in a method/process. In addition, claim 6 was rejected under 35 USC §101 for allegedly not satisfying statutory requirements.

However, claim 6 has been amended to recite a method for treating dentinal hypersensitivity in a patient. As a result, claim 6 is no longer directed to a "use" claim. As a result, applicant believes that claim 6 is definite to one of ordinary skill in the art.

In view of the above, applicant believes that claims 1-9 are definite to one of ordinary skill in the art.

In the outstanding official Action, claims 1, 2, 4, 5, 7 and 8 were rejected under 35 USC §102(b) as allegedly being anticipated by FEDOROV et al. Claims 1-3, 5, 7 and 8 were rejected under 35 USC §102(b) as allegedly being anticipated by HAKADA et al., AI, and NANBA et al. Claims 1, 2, 5 and 7 were rejected under 35 USC §102(b) as allegedly being anticipated by SHIBUYA et al. and INAHATA et al. Applicants believe that the present amendment obviates these rejections.

At the outset, applicant notes that the Office Action refers to several "technical terms". The definitions for these technical terms are provided in the Blakiston's Gould Medical Dictionary, McGraw-Hill, New York as follows:

PERIODONTIUM: the investing and supporting tissue surrounding a tooth; namely, the periodontal ligament, the gingival, the cementum, and the alveolar bone.

PERIODONTITIS: inflammation of the periodontium.

PERIODONTOSIS: a degenerative disturbance of the periodontium, characterized by degeneration of connective-tissue elements of the periodontal ligament and by bone resorption.

PERIODONTAL DISEASE: any abnormality of pathological state involving the supporting tissue of the teeth; used to designate collectively the inflammation and degenerative diseases of the periodontium.

GINGIVITIS: inflammation of the gingival.

PLAQUE FORMATION: dental plaque: a thin, transparent film on the surface of a tooth made up of mucin and colloidal material secret by salivary, mucinous and bacterial plaques.

STOMATOLOGY (and hence stomatological use): the branch of medical science concerned with the anatomy, physiology, pathology, therapeutics, and hygiene of the oral cavity, of the tongue, teeth, and adjacent structures and tissues, and of the entire body.

Applicant believes that the definitions are relevant in showing that dentinal hypersensitivity is not considered a generic "periodontal disease" but a well-defined pathology. Dentinal hypersensitivity is a distinct condition from gingivitis, periodontitis, periodontosis or periodontal disease. Indeed, explanations concerning dentinal hypersensitivity can be found, for instance, by ADDY, Int. Dental Journal (2002), 52, 367-375. A copy is attached with this amendment for the Examiner's convenience. Addy reports that:

> Dentine hypersensitivity is characterized by short, sharp pain arising from exposed dentine in response to stimuli typically thermal, evaporative, tactile, osmotic or chemical and which cannot be ascribed to any other form of dental defect or pathology.

Dentinal hypersensitivity is a condition caused by exposure of dentine to the oral environment. By way of example, factors inducing dentinal hypersensitivity are:

i) sustained and overzealous brushing, which is known to thin enamel and cause gingival to recede, exposing the softer subgingival cementum, which is also damaged by brushing. This results in hypersensitivity of teeth.

ii) age: gingival is known to recede in the elderly. This is a physiological process, which is not induced by any sort of periodontal disease.

iii) diet: habitual ingestion of acidic substances causes erosion of enamel and dentin, subsequently opening dentinal tubules and inducing dentinal hypersensitivity.

iv) tooth grinding: wears down the enamel on teeth, exposing the dentin.

v) tartar removal.

With this in mind, applicant believes that FEDOROV, HIKADA, AI, NANBA, SHIBUYA, and INAHATA each fail to anticipate the claimed invention.

FEDOROV discloses toothpaste comprising spinach.

HIKADA teaches a composition for the prevention of oral calcium phosphate precipitation (calculus formation) that contributes to the progression of gingivitis and periodontal disease. More specifically, HIKADA discloses a composition which prevents gingivitis by inhibiting the precipitation of amorphous calcium phosphate, conversely the composition of the invention prevents dentinal hypersensitivity by inducing precipitation of microcrystals which occlude the tubular orifices of the exposed

dentine, such precipitation being induced by the synergistic effect of the two plant complexes.

AI teaches a tincture for treating toothache, comprising *inter alia* rhubarb. However, a toothache is quite different from dentinal hypersensitivity which as already stated is not induced by pathological conditions such as decay, and is characterized by a different "short, sharp pain" (see Addy above).

NANBA teaches a plaque inhibitor comprising a water/methanol extract of rhubarb. Apart from any consideration of methanol toxicity, it should be stressed that dentinal hypersensitivity does not result from the presence of plaque on teeth. Therefore the purposes of these compositions are distinct from each other.

The same considerations apply for SHIBUYA (a composition for periodontosis).

INHATA teaches a deodorant for use in food, *inter alia* dentifrices and mouth cleaners, apparently for use against halitosis, which is a condition distinct from dentinal hypersensitivity. Indeed, dentinal hypersensitivity is not a cause of halitosis. Moreover, a deodorant does not necessarily alleviate pain, particularly pain due to dentinal hypersensitivity

Thus, it is believed that a composition adapted for the treatment of gingivitis, periodontitis, periodontosis or

periodontal disease is not necessarily useful for the treatment of dentinal hypersensitivity, a condition with a different etiology which results and requires a composition that relies on a different mechanism of action. As a result, applicant believes that the above-identified publication fails to disclose or suggest the claimed invention.

Claims 1-5 and 7-9 were rejected under 35 USC §103(a) for allegedly being unpatentable over FEDEROV et al. in view of HAKATA et al., AI, and NANBA et al. Applicant believes the present amendment obviates this rejection.

As noted above, none of the above-identified publications disclose or suggest a composition or method for treating dentinal hypersensitivity. As a result, applicant believes that one of ordinary skill in the art would lack the motivation to combine and modify the publications in a manner so as to obtain the claimed invention.

Claims 1-5 and 7-9 were rejected under 35 USC §103(a) as allegedly being unpatentable over GORTNER et al. and further in view of McCAY et al. and KASIDAS et al. This rejection is respectfully traversed.

Applicant believes that the GORTNER et al., McCAY et al., and KASIDAS et al. publications, alone or in combination with each other, fail to disclose or suggest the claimed invention.

GORTNER et al. disclose the effects of dietary oxalate on the teeth of white rats. The publication teaches that natural oxalate-containing foods, such as spinach and rhubarb can produce a protective film on the molars of rats within one week. Likewise, McCAY et al. teach that rhubarb juice combined with equal parts of lemon juice, may be able to protect the teeth against erosion from the consumption of acidic solutions such as cola beverages.

KASIDAS et al. teach that spinach and rhubarb compositions comprise high levels of oxalate.

However, none of the publications disclose or suggest a composition or a method for treating dentinal hypersensitivity. As a result, applicant believes that the publications, alone or in combination with each other, fail to render obvious the claimed invention.

In view of the foregoing remarks and present amendment, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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PD/mjr
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**APPENDIX**:

The Appendix includes the following item(s):

- Addy, M., "Dentine hypersensitivity: new perspectives on an old problem", International Dental Journal (2002) Vol. 52, No. 5, pp. 367-375.

- Gortner,, R.A. et al., "Some effects of dietary oxalate on the teeth of white rats", Journal of Nutrition (1946), 32, pp 121-131 (abstract).

- McCay, C.M. et al., "Erosion of molar teeth by acid beverages", Journal of Nutrition (1949), 39 pp. 313-324 (abstract).